



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

**To:** Tim Ciarlo

**From:** Eric Bohnenblust, Ph.D., Entomologist

**Secondary Review:** Jennifer Saunders, Ph.D., Lead Biologist

**Date:** February 3, 2016

**Subject:** PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

**THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION**

**Note:** MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

**DP barcode:** 430469

**Decision no.:** 507781

**Submission no:** 972241

**Action code:** R314

**Product Name:** SPCP4 Plus 1

**EPA Reg. No or File Symbol:** 2517-RTT

**Formulation Type:** Dog Collar

**Ingredients statement from the label with PC codes included:**

Deltamethrin 4.0% PC: 097805

Pyriproxyfen 1.0% PC: 129032

**Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m<sup>2</sup> or mg/cm<sup>2</sup> or mg/kg body weight as appropriate):** Small collar 0.65 oz. fits up to 15" neck size; Medium collar 0.85 oz. fits up to 20" neck size; large collar 0.97 oz. fits up to 23" neck size

**Use Patterns:** Dog collar to control fleas and ticks.

**I. Action Requested:** Review the submitted MRIDs to support label claims against fleas and ticks, including insect growth regulator (IGR) type claims for the proposed dog collar containing deltamethrin and pyriproxyfen.

**II. Background:** The registrant submitted a dog collar product containing deltamethrin and pyriproxyfen to control fleas and ticks. This is a new product and the data are intended to support claims for up to 6 months and IGR type claims. MRIDs 44578702-5 and 44602901 were previously reviewed to support a similar 4% deltamethrin dog collar with efficacy claims against ticks. Brief overviews of the methods, results, and conclusions for these MRIDs as they relate to the proposed product are below.

**III. MRID Summary:**

**A. Newly Cited studies:**

**43722809. The Evaluation of the Efficacy of Q-Sect IGR Flea Collar on Cat Flea Control on Dogs.**

(1) GLP

(2) **Methods:** Twenty dogs were tested for their ability to maintain flea populations, and of these twenty dogs, eighteen qualified for the efficacy trial. These eighteen dogs were split into three groups of 6 dogs. On test day – 7, the Group A dogs were given a nylar (aka: pyriproxyfen) impregnated collar with an initial weight of approximately 12 g product, Group B dogs were also given a nylar collar impregnated with an initial weight of approximately 12 g of product, and Group C was an untreated control (no collars). The percentage of nylar present in the collar was not given. In both Group A and B, approximately 9 g of product was released throughout the experiment (assumed to be 363 days). On test days 0, 7, 14, 21, 28, 35, 42, 49, 63, 77, 91, 105, 119, 133, 147, 161, 175, 189, 202, 217, 230, 263, 273, 286, 301, 312, 329, 350, 363 dogs were infested with between 100 and 200 adult fleas. Four days after inoculation, approximately 100 ova were collected from each dog in each treatment group. If less than 100 ova was collected from a dog, ova from another dog within the same treatment were supplemented to get 100 ova per dog. Ova were observed for hatching 72 hours after collection. Efficacy against adults was determined at 35 days post each inoculation and calculated as percent efficacy based on adult emergence in the control treatment. However, other methods for evaluating adult efficacy are not given.

(3) **Results:** Both collar treatments reduced the emergence of fleas by over 90% through day 367. In the control treatment, 30-50% of the eggs hatched into larvae on most evaluation dates. Adult emergence was low for most of the study, but it is unclear if the number of adults recorded was a subset of larval emergence or in addition to larval emergence.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims against fleas because: the percentage of pyriproxyfen in the test collars is not provided; methods for evaluating efficacy against adults are not adequately provided; it is not clear how many fleas emerged in the control treatments (were adults and larvae considered separately?); the number of adult fleas emerged is listed as percent live developed in the tables so we don't know what this number represents; it is not clear when the "on-animal" portion ended (the reviewer assumed it to be 363 days). Moreover, flea eggs in this study were at most a week old, but it can take up to two weeks for flea eggs to hatch. The age of the eggs might account for some of the low hatch rates on some days, and if eggs received a sublethal dose of pyriproxyfen, hatch may have been delayed in the treatment groups an effect which is not accounted for in this study.

#### 44190101. Deltamethrin Dog Collars—Efficacy Studies.

(1) unknown if GLP

(2) **Methods:** This MRID contains brief summaries of 6 experiments testing 3% and 4% deltamethrin collars on dogs against fleas and ticks. Details are outlined below for each individual study.

Study 1: This study tested the efficacy against fleas and brown dog ticks of a 3% deltamethrin collar, a 4% deltamethrin collar, and a commercial collar containing 15% diazinon. Efficacy was evaluated through 462 days post application.

Study 2: Twenty four dogs were split into 3 groups of eight: one group was treated with a 3% deltamethrin collar, one group received a 4% deltamethrin collar, and the third group received an Escort® collar of with an unknown active ingredient. These collars were tested on dogs for efficacy against cat fleas, brown dog ticks, and American dog ticks for one year.

Study 3: Thirty two dogs were split into 4 groups of eight: one group was treated with a 3% deltamethrin collar, one group received a 4% deltamethrin collar, one group served as an untreated control, and the fourth group received a commercial collar of with an unknown active ingredient. These collars were tested on dogs for efficacy against cat fleas and brown dog ticks. Periodically dogs were infested with 100 adult fleas and 50 brown dog ticks. After infestation, fleas and ticks were counted to determine efficacy.

Study 4: The study tested the efficacy of three collars on dogs against the brown dog tick. Eight dogs served as a control group, eight dogs wore a collar (Russel UCLF) treated with 4% deltamethrin, eight dogs wore a Bayer Kiltix



collar, and eight dogs wore a Virbac Preventic collar. Collars were placed on dogs on study day 0. Dogs were infested with 25 brown dog ticks on days -2, 7, 14, 30, 60, 90, 120, 150, 180, and 210. Counts of “knockdown mortality” were made 24, 48, and 72 hours after all infestation dates except for day -2. Efficacy was evaluated 24, 48, and 72 hours after application of the collar on day 0.

Study 5: This study tested dog collars containing an unknown amount of deltamethrin against brown dog ticks on an unknown number of dogs (at least 6 dogs) and there were 20 untreated dogs. Dogs wore the collars for 180 days.

Study 6: This study tested dog collars containing an unknown amount of deltamethrin against fleas on an unknown number of dogs (at least 6 dogs). Dogs wore the collars for 195 days.

### **(3) Results:**

Study 1: Control of fleas in the 4% deltamethrin collar treated was between 80-95% through 210 days post application of the collars. After 210 days, efficacy of the 4% collar was over 90% but this was because two dogs were dropped from the experiment in the 4% deltamethrin treatment group because they continually harbored higher numbers of fleas than the other dogs. Efficacy of the 3% deltamethrin collar against fleas ranged from 85-95% through day 77 and then jumped to over 90% from day 105 until day 378 after which efficacy against fleas was around 80%. Efficacy of both deltamethrin against ticks was 87% on day 3 and then over 90% through day 118. After day 118, efficacy of the deltamethrin collars was highly variable ranging from 64-92%. This study does not support efficacy claims because there was no untreated control, the endpoint (mortality, knockdown) is not clear, the method for calculating percent mortality is not clear, and the rest of the methods are inadequate for review.

Study 2: The 4% deltamethrin collar provided between 82 and 97% control of fleas and 96 to 100% control of ticks throughout the study. The 3% deltamethrin collar was “slightly less effective”. This study does not support efficacy claims because the methods are inadequate for review, the Agency requires 90% mortality consistently, and we do not use “slightly less effective” as a level of control to support efficacy claims.

Study 3: The 4% deltamethrin collar “completely” controlled fleas from day 30 – 378, and provided “good” of both tick species through day 300. The 3% deltamethrin collar was “slightly less effective” through 300 days. This study does not support efficacy claims because the methods are inadequate to accurately review, and the Agency does not use “complete”, “good” or “slightly less effective” as levels of control to support efficacy claims.

Study 4: After the application of the Russell UCLAF deltamethrin collar, “knockdown mortality” only reached 78% by day 3. Mortality after that is only listed as being greater than 80% for this collar. This study does not support efficacy claims for a 4% collar because knockdown is not defined, efficacy was not consistently over 90%, most of the data were not provided, and the methods were inadequate to accurately review.

Study 5: The collars provided “complete” control through 90 days. The effect of the collars started between 24 hours and 20 days after application. Tick populations were not high enough to evaluate efficacy through 180 days post application. This study does not support efficacy claims because the methods are inadequate for review, the agency does not use complete vs. incomplete protection to support efficacy claims, and efficacy needs to occur more quickly than 20 days after application.

Study 6: The collars tested provided “complete” protection from day 6 post application to day 90, and then “incomplete” protection from day 90 through day 195. This study does not support efficacy claims because the methods are inadequate and the agency does not use complete vs. incomplete protection to support efficacy claims.

**(4) Conclusion: Unacceptable.** These studies do not include enough information to adequately evaluate the studies and therefore these data do not support the proposed product.

### **B. Previously Reviewed Studies:**

**44578702. Review of the Anti-feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies.**

(1) non-GLP

(2) **Methods:** This MRID is a document summarizing numerous published manuscripts covering the effects of deltamethrin and permethrin against mosquitoes and sandflies. There are one or two summarized studies that were conducted with dog collars containing deltamethrin; however, the original studies containing data were not submitted to EPA.

(3) **Conclusion: Extraneous submission.** This is not an original scientific study and the MRID discusses the effect of deltamethrin against mosquitoes and sandflies. The label does not have any claims against mosquitoes or sandflies and this study would not be sufficient to support claims.

**44578703. Initial Kill Activity of Deltamethrin 4% Collars against *Ixodes scapularis* Nymphs Using Treated Dog Hair as the Testing Substrate.**

(1) GLP

(2) **Methods:** Eight dogs were treated with a 4% deltamethrin collar and eight dogs received a placebo control on test day 0. On day 42, hair samples weighing 0.5-1 g were clipped from three locations, the collar area, midline dorsal, and the base of the tail. Hair samples were placed into petri dishes, and hair from each location was tested separately and additionally a treatment consisting of hair from all three locations mixed together was also tested. Each petri dish was inoculated with 10 deer tick nymphs. Mortality of ticks was assessed at 24 and 48 hours after exposure to treated hair.

(3) **Results:** Over 90% of ticks were dead in petri dishes containing treated hair collected from the area around the collar and the petri dishes with mixed hair at 24 hours post inoculation. In the petri dishes with hair collected from the dorsal midline or the base of the tail, mortality of deer tick nymphs was 77% and 87% respectively at 24 hours post inoculation. Over 90% of ticks were dead in petri dishes containing treated hair collected from all locations at 48 hours post inoculation. The percent of dead ticks in the control dishes ranged from 15-40%.

(4) **Conclusion: Supplemental.** This study shows that residues of deltamethrin from a 4% collar on dog hair can kill nymphal deer ticks, but it cannot, by itself, support efficacy claims because studies should be performed on animals with adult ticks, efficacy was not tested at various early time points (e.g., immediately after applying collars, 7 days post) so we do not know when the collar starts to work, control mortality was too high, and the study only tested at 42 days and the label claims are for 6 months.

**44578704. Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in Dogs.**

(1) non-GLP (Conducted under GCP)

(2) **Methods:** In this study 10 dogs served as untreated control animals and 10 dogs were treated with a 4% deltamethrin collar. Dogs were infested with 20 *I. ricinus* and 20 *R. sanguineus* on day -1 prior to treatment and days 7, 28, 56, 84, 112, 140, 154, and 168 post treatment. Efficacy was determined as the number of live ticks on treated vs. untreated dogs at 24 and 48 hours post treatment (treatment occurred on day 0) or infestation.

(3) **Results:** Efficacy of the deltamethrin collar against both tick species was approximately 80% 48 hours after treatment. Efficacy against both ticks species at 48 hours after all infestations from day 7 through 154 was over 90%. At 168 days post treatment, efficacy against both tick species was less than 75%.

(4) **Conclusion: Partially Acceptable.** This study shows efficacy against *Ixodes ricinus* and *R. sanguineus* through 5.5 months post treatment. This study does not show efficacy against the two tested tick species at 6 months. This study supports two of the three tick species required to support claims against ticks; data must also be submitted that show efficacy of the product against American dog ticks (*Dermacentor variabilis*) for any claims against ticks.

**44578705. Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of**



#### **Adult *Aedes aegypti* Mosquitoes.**

(1) GLP

(2) **Methods:** This study tested the efficacy of a 4% deltamethrin dog collar against *Aedes aegypti* mosquitoes.

(3) **Conclusion: Extraneous submission.** There are no label claims for mosquitoes, therefore this study is extraneous.

#### **44602901. Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in dogs.**

(1) non-GLP

(2) **Methods:** This MRID documents a field study which tested the efficacy of 4% deltamethrin collars on dogs against *Ixodes ricinus* and *Rhipicephalus sanguineus* for up to 7 months. In this study, collars were applied to 88 dogs. There was an unknown number of untreated dogs in the areas where dogs were exposed to natural tick infestation and they were used to detect tick activity in those areas. Of the 88 treated dogs, 79 were naturally infested with *I. ricinus*, and 9 were naturally infested with *R. sanguineus*. Efficacy of the collars was evaluated by the observation of dead ticks at unknown dates and times. Because six dogs lost collars before 5 months, the duration of efficacy was only evaluated on 82 dogs.

(3) **Results:** The level of efficacy achieved at different time points is not clear, although it seems to be considered 100%. However the study also says that collars were worn until tick infestations were zero and there does not appear to be any method of assessing if ticks drop off the animal and are still alive during the course of the study. The duration of efficacy claimed in the study is 7 months for 4.5% of dogs, 6 months for 64.8% of dogs, and 23.9% of dogs, the other 6.8% of dogs were not evaluated for the duration of efficacy because their collars went missing before month 5.

(4) **Conclusion: Unacceptable.** This MRID is not acceptable because the data do not show a concrete level of efficacy, the raw data are not provided, and the level of efficacy necessary to achieve the duration of efficacy described in the study is not clear.

#### **IV. EXECUTIVE DATA SUMMARY:**

(A) The submitted data do not support efficacy claims against any of the public health pests listed on the label.

The submitted data show efficacy against *Ixodes* ticks and brown dog ticks; however, for any claims against ticks to be supported, data must be submitted showing efficacy of the proposed product against American dog ticks (*Dermacentor variabilis*).

The submitted data do not support adulticide or IGR types of efficacy claims against fleas.

#### **V. LABEL RECOMMENDATIONS:**

(1) List changes to the directions for use: Delete all references of use against fleas or ticks.

(2) The following marketing claims are acceptable:  
No claims are supported by the submitted data.

(3) The following marketing claims are unacceptable:  
All claims related to fleas and ticks are unacceptable.

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 44578702, 44578705, 43722809, 44602901, and 44190101.